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Subject: EPA To Avoid Controversial Laboratory Data In Fuels Risk Assessments

Daily News

EPA To Avoid Controversial Laboratory Data In Fuels Risk Assessments

Posted: March 8, 2012

EPA has announced that it will not use cancer data from a controversial Italian laboratory for its ongoing risk assessments of methanol and the fuel additives methyl tertiary butyl ether (MTBE) and ethyl tert-butyl ether (ETBE), after a lengthy pathology review of the lab's data confirmed preliminary findings that it overestimated cancer risks.

However, the agency suggests in a March 8 statement that it will continue to use the Ramazzini Institute's cancer data in its existing assessment for vinyl chloride because the review generally agreed with the lab's results. And the agency says it has sidestepped concern with its draft acrylonitrile assessment because it has relied on data from sources "other than the Ramazzini" to complete the draft assessment.

The agency's decision is winning praise from industry groups, who have long feared that EPA's use of the institute's data will result in overly conservative risk assessments – and corresponding regulatory standards. "This would seem to be a win for those of us who have been questioning the use of the Ramazzini data for several years," says one industry source.

Industry has long charged that the institute's data overestimates cancer risks and have criticized EPA's use of the data in its Integrated Risk Information System (IRIS) risk assessments.

The issue came to a head in the case of EPA's draft methanol assessment, where the industry groups charged that the lab's unique approach to cancer bioassays led to inaccurate results – thus leading EPA to overestimate methanol's cancer risk to humans.

A 2010 review of some of Ramazzini's methanol study results by the National Toxicology Program (NTP) raised questions about the results and methods of Ramazzini's studies on methanol's carcinogenicity and found a lower incidence of lymphoma or leukemia in Ramazzini's test rats exposed to methanol than Ramazzini scientists found.

This prompted EPA to halt work on four pending draft assessments that contained data from the institute -- including those of methanol, MTBE, ETBE and the plastic ingredient acrylonitrile -- as well as existing assessments of vinyl chloride and 1,1 dichloroethylene (DCE), which were published on the IRIS website in 2000 and 2002 respectively.

NTP, together EPA, assembled a pathology working group (PWG) whose members traveled to the Ramazzini lab in spring 2011 to perform a more extensive review of the five studies EPA had relied on.

The PWG completed its report last November but the agencies' delay releasing it prompted concern from Republicans, including Sens. James Inhofe (OK) and David Vitter (LA) and Reps. Paul Broun (GA) and Andy Harris (MD) who recently called for its speedy release.

Now, NTP has released the PWG's results which confirm the earlier findings that the lab had overestimated cancer risks of methanol, as well as those for MTBE and ETBE. “The report pointed out some instances where the presence of respiratory infections in [Ramazzini] study animals made definitive diagnoses difficult, and that some [Ramazzini] diagnoses, primarily certain leukemias and lymphomas, were not considered to be malignant tumors. As a result, PWG scientists found fewer numbers of leukemias and lymphomas than had been originally reported by the [Ramazzini],” according to EPA's March 8 statement.

As a result of these “differences of opinion,” EPA has decided not to rely on the Ramazzini studies for the three ongoing assessments.

EPA adds that “There was good agreement between the [Ramazzini] and PWG scientists in diagnosing solid tumors such as liver tumors from the [Ramazzini Institute] study on vinyl chloride. EPA has therefore decided to continue to consider [Ramazzini] solid tumor data in IRIS assessments. [The institute's] solid tumor findings will be reviewed along with other data in determining the overall weight of evidence of carcinogenicity for substances on which EPA is conducting IRIS assessments.”

The agency notes that the draft acrylonitrile assessment “is not affected, as EPA relied on data from sources other than the Ramazzini Institute to complete the draft assessment.” EPA released its draft assessment of that chemical in June, and is scheduled to complete the assessment in 2013, according to the agency's IRIS Track website.

It is not clear what the PWG report means for the agency's DCE assessment.

Different Methods

The Ramazzini data has proven controversial largely because the lab's methods differ greatly from U.S. counterparts. EPA and other federal agencies tend to use lab rodent studies of specific duration -- generally two years -- to make decisions about chronic exposure to chemicals. They also often use pathogen-free strains of animals in labs with pathogen barriers, to avoid confounding infections.

The Ramazzini labs have a totally different perspective. The labs' science director Morando Soffritti told *Inside EPA* in a spring 2010 interview that his lab's study design -- eschewing pathogen-free animals and facilities and allowing the animals to die naturally -- better mimics human life.

American critics, however, argue that these decisions lead to confounding. In recent years, industry consultant George Cruzan and EPA scientists have authored several papers with competing explanations for an infection or lack of infection in the Ramazzini rats' lungs that could be confounding the studies' results. Some industry sources have even suggested that the location of the Ramazzini lab, housed in a fifteenth century castle, could exacerbate the lab animals' respiratory infections.

To address this, EPA notes in its statement that the PWG recommended changes in Ramazzini "laboratory procedures and EPA hopes that [Ramazzini] will fully implement these recommendations to allow for the use of future [Institute] data in IRIS assessments." -- *Maria Hegstad* (mhegstad@iwpnews.com) This e-mail address is being protected from spambots. You need JavaScript enabled to view it)

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